DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 14, 16, 20-21, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shettigar (GB 2124511) in view of Baudet et al. (USP 4,038,190) and further in view of Kolff et al. (USP 4,663,049).

Regarding claims 14 and 16, Shettigar discloses an apparatus for the purification of blood (Abstract) in figure 1 and annotated figure above, comprising:

- A duct for the flow of whole blood (1 - conduction system)
- A stage for filtering plasma from the whole blood arranged along said duct (filter 15 for instance)
- A plasma purification circuit and connected with the plasma filtering stage (see annotated figure above)

- A stage for whole blood dialysis by means of plasma purified in said circuit, said stage for whole blood dialysis comprising a selectively permeable interface for separating at lease part of the whole blood stream of said duct from a countercurrent stream of plasma purified in said circuit (2, see also P4/L1-40).

Shettigar discloses all of the claim limitations as set forth above. Shettigar does not explicitly disclose the parallel permeable capillaries separated by a wall with a gap in the wall.

Baudet et al. discloses a hollow fiber fluid fractioning apparatus (abstract) in figure 23 comprising:

- A core (1 - which acts as the wall between the chambers)
- Tubes (12 and 13) for plasma flow
- Tubes (17 and 18) for blood flow
- Orifice (14) through which fluid passes in the core from hollow fiber set one to the second set (2 and 2' are hollow fiber or capillaries).

Shettigar and Baudet et al. are combinable because they are concerned with the same field of endeavor, namely that of membrane units.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dialysis separation system of Shettigar to replace the hollow fiber unit (2) of Shettigar with the membrane system as disclosed in figure 2 of Baudet et al. for the purpose of improved fluid purification in a counter current operation system.

Shettigar as modified above further discloses a second fraction of venous purified plasma returns to the dialyzer. However, Shettigar fails to explicitly disclose having a fraction returned and mixing with the blood components to be returned to the patient.

Kolff et al. discloses in figure 1 a process of separating plasma from blood components, dialyzing plasma, and finally recombining plasma with blood components prior to returning it to the patient.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Shettigar to further include a first fraction of purified plasma being mixed and recombined with patient blood prior to return to the patient as taught by Kolff for the purpose of providing for volume replenishment of the patient (e.g. if the plasma is not returned, then the patient will be hemodynamically unstable due to hypovolemia which would lead to hypovolemic shock, a commonly well known undesired condition).

Regarding claims 20 and 21, Shettigar further discloses the unit (15) has a carbon adsorptive cartridge (P4/L83-105 - cartridge would be equivalent to column).

Regarding claims 27 and 28, Shettigar further discloses use of a circuit pump (13 - filtrate pump) and a blood pump (P3/L1-13).

4. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shettigar (GB 2124511) in view of Baudet et al. (USP 4,038,190) in view of Kolff et al. (USP 4,663,049), and further in view of Mishiro et al. (USP 4,340,481).

Regarding claims 17-19, Shettigar discloses all of the claim limitations as set forth above. Shettigar does not explicitly set forth a dialyzer system assembly which utilizes a dialysate tank, used dialysate tank, and an infusate tank.

Mishiro et al. discloses a membrane filtration hollow fiber system (Abstract) in figure 10 comprising:

A dialysate tank, a dialyzer, an infusate tank, and a used dialysate tank.

Shettigar and Mishiro et al. are combinable because they are concerned with the same field of endeavor, namely that of membrane units.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the purification loop of Shettigar to further include a membrane dialyzer with assorted tanks as taught by Mishiro et al. for the purpose of improved dialysis performance and reduced risk of infection.

Response to Arguments

5. Applicant's arguments filed 11/27/2009 have been fully considered but they are not persuasive.

- Applicant alleges Shettigar only provides for a regenerated blood filtrate and not purified plasma.

This argument is not convincing. The regenerated blood filtrate will be of specific composition that could pass through the dialyzer; this dialyzer intended to prevent blood

from passing into the filtrate circuit (P3/L14-26). Thus, one of ordinary skill would recognize based on the Mw cutoffs discussed, that plasma would be capable and would in fact pass over into the filtrate circuit and it is further noted that plasma would make up a significant portion of the dialysate solution. Applicant's claims do not restrict the possibility of other blood components from being in the filtrate.

- Applicant alleges there is no teaching to provide the dialyzer of Baudet into the system of Shettigar.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there would be improved filtration performance.

With respect to Applicant's arguments with regards to the venous return discussion, see above new grounds of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 9:00am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1797

/D. C. M./
Examiner, Art Unit 1797